IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ROBERT T. PRITCHARD and ELIZABETH ANN PRITCHARD, Plaintiffs, v. DOW AGRO SCIENCES, a division of DOW CHEMICAL COMPANY, SOUTHERN MILL CREEK PRODUCTS OF OHIO, and RESIDEX PRODUCTS, Defendants.	)	Civil Action No. 07-1621 Judge Nora Barry Fischer

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the Court is Defendants Dow Agro Sciences ("Dow") and Southern Mill Creek Products of Ohio's ("Southern Mill") *Daubert* motion challenging Plaintiffs Robert T. Pritchard and Elizabeth Ann Pritchard's proffer of expert testimony by Dr. Bennet Omalu. (Docket No. 127). Dr. Omalu opines that Mr. Pritchard's exposure to Dursban products, which were manufactured and sold by Defendants, caused him to develop Non-Hodgkin's Lymphoma ("NHL"). Defendants maintain that Dr. Omalu is not qualified to render his opinions in this case. They also argue that Dr. Omalu's opinions regarding both general causation and specific causation do not meet the reliability standards set forth in *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579 (1993), and incorporated into Federal Rule of Evidence 702, and that his opinions do not fit the facts of this case.

The motion has been fully briefed and the Court heard oral argument[1] from counsel on November 17, 2009. Upon consideration of the parties' arguments, and for the following reasons, Defendants' motion [127] is GRANTED.

II. BACKGROUND[2]

A. Factual Summary

The instant lawsuit is a toxic tort case in which Mr. Pritchard and his wife allege that chemicals manufactured and sold by Defendants Dow and Southern Mill caused Mr. Pritchard to develop NHL. (Docket No. 23 at ¶¶ 7-10, 20). Mr. Pritchard asserts claims of negligence and strict liability against Defendants, while Mrs. Pritchard asserts a claim for loss of consortium. (Docket No. 23). Plaintiffs do not claim any injuries to Mr. Pritchard caused by Defendants except those resulting from his development of NHL. (Docket No. 128-1, Exhibit 2, *Email from David Rodes, Esq. to William Padgett, Esq.* at 1).

Mr. Pritchard was diagnosed with NHL, specifically Diffuse Large B-Cell Lymphoma, not otherwise specified ("DLBCL NOS"), a form of cancer, in August of 2005. (Docket No. 128-1, Exhibit 3, *Plaintiffs' Answers to Dow Agro Sciences LLC's First Set of Interrogatories to Plaintiffs dated Aug. 25, 2008*). After treatment, his NHL went into remission in November of 2005. (*Id.*).

---

[1] The Court scheduled a hearing on the *Daubert* motion and invited the parties to present testimony and other evidence during the hearing. Both parties declined the invitation, instead relying on the briefs and evidence previously submitted. (Docket No. 152 at 3).

[2] As the parties are well aware of the factual and procedural background of this case, the Court will limit its discussion to the background necessary for the resolution of the current motion. For further detail regarding same, *see Pritchard et al. v. Dow Agro Sciences, et al.*, 255 F.R.D. 164 (W.D.Pa. Jan. 5, 2009), 2009 WL 1813145 (W.D.Pa. June 25, 2009), 273 F.R.D. 277 (W.D.Pa. Nov. 12, 2009).

The parties do not dispute that Mr. Pritchard was diagnosed with NHL or DLBCL NOS. (Docket No. 152 at 42). The dispute surrounds whether Mr. Pritchard's exposure to Dursban products, and its active ingredients, including chlorpyrifos, is a legal cause of his disease.

The National Cancer Institute defines NHL as "[a]ny of a large group of cancers of lymphocytes (white blood cells)." *Non-Hodgkin['s] Lymphoma, National Cancer Institute*, available at: http://www.cancer.gov/cancertopics/types/non-hodgkin (last visited 3/5/10). NHL is a cancer that begins in cells of the immune system and can affect most areas of the human body. *What You Need to Know About Non-Hodgkin['s] Lymphoma*, National Cancer Institute, U.S. Department of Health and Human Services, National Institute of Health, at 2-3, available at: http://www.cancer.gov/cancertopics/wyntk/non-hodgkin-lymphoma.pdf. (last visited 3/5/10). DLBCL is "[a] type of B-cell non-Hodgkin['s] lymphoma (cancer of the immune system) that is usually aggressive (fastgrowing). It is the most common type of non-Hodgkin['s] lymphoma, and is marked by rapidly growing tumors in the lymph nodes, spleen, liver, bone marrow, or other organs. Other symptoms include fever, night sweats, and weight loss. There are several subtypes of diffuse large B-cell lymphoma." *Id.* at 32. One of the subtypes of DLCBL is DLCBL NOS. (Docket No. 128-5, Exhibit 11, International Agency for Research on Cancer, *WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues ("WHO Classification Study")*, at 233 (4th ed. 2008)). The American Cancer Society estimated that 65,980 new cases of NHL would occur in 2009. (Docket No. 128-1, Exhibit 5, *American Cancer Society, Cancer Facts & Figures Excerpt - 2009 ("ACS Excerpt")* at 15). The incidences of NHL have nearly doubled since the 1970s. *Id.* This increase is largely unexplained. *Id.* The World Health Organization estimates that 25-30% of adult NHLs in western countries are DLCBL NOS. *WHO Classification Study* at 233.

The etiologies or causes of NHL and its subtype, DCLCBL NOS, are generally unknown. *Id.; see also ACS Excerpt* at 15. But, several risk factors have been identified, including: people with severe immunodeficiency, human immunodeficiency virus (HIV), human T-cell leukemia virus type 1, hepatitis C virus; a family history of NHL; and occupational exposure to herbicides, chlorinated organic compounds and certain other chemicals. *Id.*

Dursban is a registered trademark owned by Dow Agro Sciences LLC. (Docket No. 128 at 4). "Dursban is the trade name for a group of insecticide products containing chlorpyrifos as the active ingredient." (*Id.*). The other ingredients in Dursban are Xylene-range aromatic solvents including Xylene, Cumene, and Ethyltoluene. (Docket No. 128-9, *Material Safety Data Sheet for Dursban L.O. Insecticide*). "Chlorpyrifos was widely used in U.S. households until 2000, when the U.S. Environmental Protection Agency revised its risk assessment of this and other organophosphate pesticides and phased out or eliminated certain residential uses." (Docket No. 138-5, Won Jin Lee et al., *Cancer Incidence Among Pesticide Applicators Exposed to Chlorpyrifos in the Agricultural Health Study ("2004 Lee Study"),* 96 J. Nat. Cancer Inst. 1781 (2004) at 1). Among other chemicals evaluated, the EPA has classified chlorpyrifos in Group E: Evidence of Non-Carcinogenicity for Humans. (Docket No. 128-9, Exhibit 24, *List of Chemicals Evaluated for Carcinogenic Potential*). The other categories include Group A: Human Carcinogen; Group B1: Probable Human Carcinogen; Group C: Possible Human Carcinogen; and, Group D: Not Classifiable as to Human Carcinogenicity. (*Id.*).

B. Procedural History as to the Instant Motion

In support of their claim that Mr. Pritchard's exposure to Dursban caused his NHL, Plaintiffs identified Dr. Bennet Omalu as their expert on medical causation and submitted his expert report to

Defendants on June 1, 2009. (*Dr. Omalu Report* at 1). Thereafter, Plaintiffs supplemented Dr. Omalu's expert report by providing Defendants with a series of articles upon which Dr. Omalu relied. Dr. Omalu was then deposed on June 26, 2009. (Docket No. 128-1, *Dr. Omalu deposition* at 1).

Defendants filed their Motion to Exclude the Expert Causation Testimony of Dr. Bennet Omalu on July 22, 2009. (Docket No. 127). In support of their motion, Defendants attached voluminous exhibits including rebuttal experts reports authored by Marshall A. Lichtman, M.D., Seymour Grufferman, M.D. and Michael Greenberg, M.D. (Docket Nos. 128-1 through128-9). Plaintiffs filed their Brief in Opposition to Defendants' Motion to Exclude on August 28, 2009, attaching the "Declaration of Bennet I. Omalu, MD, MBA, MPH." (Docket No. 135).[3] In response, Defendants filed their Reply brief on November 2, 2009, and a second appendix, including a rebuttal declaration from Seymour Grufferman, M.D. (Docket No. 149). The Court held a *Daubert* hearing on November 17, 2009 during which the parties presented no additional evidence, only arguing the legal issues in dispute.

After the *Daubert* hearing, the parties submitted supplemental briefing on whether the exclusion of Dr. Omalu's testimony violated the *Erie* doctrine, an argument which was raised and then more fully developed by Plaintiffs at the hearing. *See Erie Railroad Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Defendants filed their supplemental brief on January 4, 2010, while Plaintiffs submitted their supplemental brief on January 25, 2010. (Docket Nos. 154, 155).

In sum, the proffer of Dr. Omalu's testimony consists of opinions outlined in his expert

---

[3] Defendants brought a motion to strike Dr. Omalu's declaration. (Docket No. 137). The legal issues pertaining to same were fully briefed by the parties, oral argument was held, and the Court denied Defendants' motion to strike for reasons stated in a written decision. (Docket No. 150); *Pritchard*, 263 F.R.D. 277 (W.D.Pa. Nov. 12, 2009).

report, portions of his deposition testimony and his declaration. Defendants take issue with this proffer.

III. DISCUSSION

In this action, both parties test the boundaries of Federal Rule of Evidence 702 and *Daubert* and the admissibility of a medical causation opinion by an expert in a toxic tort case. Defendants take a restrictive view of Rule 702, *Daubert* and its progeny, arguing that several deficiencies in Dr. Omalu's proffered testimony independently render his opinions *per se* inadmissible, requiring exclusion of Dr. Omalu without further analysis. Plaintiffs' position is much more liberal, and they maintain that their proffer is sufficient to meet the minimal requirements of Rule 702, *Daubert* and its progeny, arguing that Dr. Omalu's testimony should not be excluded. Alternatively, Plaintiffs contend that the application of certain principles advocated by Defendants violates the *Erie* doctrine. The Court has carefully considered the parties' respective positions and, based on the present record, finds that the methodology used by Dr. Omalu in reaching his opinions in this case is not reliable and, even if it was found to be reliable, his opinions are too speculative to "fit" the facts of this case. Accordingly, Plaintiffs have failed to establish that there are "good grounds" for permitting him to so testify.

A. *Legal Standard*

Federal Rule of Evidence 702, which memorializes the Supreme Court's landmark case *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provides the basic framework for the admissibility of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience,

> training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED.R.EVID. 702.[4] The United States Court of Appeals for the Third Circuit has held that "Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)(citations omitted). "[T]he district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury." *Id*. In this role, the district court is not the finder of fact but must focus on the methodology of the expert in order to "satisfy itself that 'good grounds' exist for the expert's opinion." *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (citing *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786); *In re TMI Litigation*, 193 F.3d 613, 713 (3d Cir. 1999)(district court should not conflate "its gatekeeping function with the fact-finders' function as the assessor of credibility").

> *Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony rests upon "good grounds, based on what is known," it should be tested by the adversary process-competing expert testimony and active cross-examination-rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies. In short, *Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable

---

[4] FED R. EVID. 702 was amended in 2000 in response to *Daubert*, but pre-2000 precedent regarding the *Daubert* analysis also applies to the analysis under Rule 702. *See, e.g., Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).

fashion.

Mitchell, 365 F.3d at 244 (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)(citations omitted)*; see also Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 809 (3d Cir. 1997)("The trial judge must be careful not to mistake credibility questions for admissibility questions.").

Finally, the party asserting the admissibility of the proffered testimony has the burden to demonstrate by a preponderance of the evidence that the opinions are based on "good grounds." *Kannankeril*, 128 F.3d at 807.

B. Expert Opinions

1. Plaintiffs' Expert - Dr. Bennet I. Omalu

Dr. Bennet I. Omalu is currently the Chief Medical Examiner of San Joaquin County, California and was formerly the Attending Forensic Pathologist and Neuropathologist in the Allegheny County Coroner's Office from 2002 until 2007. (Docket No. 128-9, Exhibit 31, *Robert T. Pritchard, Sr., Medico-Legal Report by Dr. Bennet I. Omalu ("Dr. Omalu Report")* at 1, 5). He is also co-director of the Brain Injury Division at the Rockefeller Institute of Neuroscience, and an Associate Clinical Professor of Pathology at the University of California, Davis. (*Id*. at 5). He is board certified in Anatomic Pathology, Clinical Pathology, Forensic Pathology and Neuropathology and has a Master's degree in Public Health-Epidemiology from the University of Pittsburgh. (*Id*.). He is licensed to practice in Indiana, Pennsylvania, Hawaii, and California. Thus, Dr. Omalu has significant expertise in the fields of pathology and epidemiology.

Dr. Omalu prepared an expert report for purposes of this litigation. He did not conduct a physical exam of Mr. Pritchard, nor did he meet with him. (*Dr. Omalu Deposition* at 43, 246). Prior

to preparing his report, Dr. Omalu reviewed the following documents: Plaintiffs' Second Amended Complaint; a medical report by Dr. Emilio Navarro, MD[5], dated April 22, 2008; a surgical pathology report, S-05-0009357, from the Uniontown Hospital Laboratory, Uniontown, Pennsylvania, dated September 1, 2005; and, a Material Safety Data Sheet ("MSDS") on Dursban L.O. Insecticide from Dow AgroSciences, Calgary, Alberta. (*Omalu Report* at 2). Dr. Omalu admitted that he did not review all of Mr. Pritchard's medical records, testifying that he did not believe it was necessary in order to render his opinions. (*Dr. Omalu Deposition* at 38-40, 41-44). He also did not review any of Mr. Pritchard's pesticide application records, Plaintiffs' discovery responses, Mr. Pritchard's deposition transcript, all of which contain information regarding the extent of Mr. Pritchard's exposure to Dursban and other pesticides, or any documents related to Dursban products other than the MSDS sheet on Dursban L.O. (*Dr. Omalu Deposition* at 45-55).

In his Report, Dr. Omalu concludes that Mr. Pritchard's "prolonged occupational exposure to Dursban insecticides significantly contributed to the patho-etiology of his Non-Hodgkin's Lymphoma."[6] (*Dr. Omalu Report* at 2). Dr. Omalu first describes the general risk of exposure to pesticides to humans, stating that "[a]ssessment of the risk of agricultural toxins, insecticides and herbicides to humans has shown that these chemicals are highly toxic and dangerous and have been

---

[5] Dr. Emilio Navarro was initially identified as Plaintiffs' expert on medical causation in this case when Plaintiffs were still represented by Douglas Sholtis, Esquire. *Pritchard*, 277 F.R.D. at 280. He has since been withdrawn as an expert. *Id*. His initial report and addendum are filed of record. (Docket No. 128-9, Exhibits 28, 29).

[6] The Court notes that Dr. Omalu's report consists of four and one-half pages, single spaced and contains only one citation to authority, HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, *Kasper, Braunwald, Fauci, Hauser, Longo, Jameson eds.* 16th edition. McGraw-Hill, Medical Publishing Division, New York, 2005. (*Dr. Omalu Report*).

identified as human carcinogens." (*Dr. Omalu Report* at 2). He opines that "no level of exposure to agricultural chemicals should be deemed safe" because they are not indigenous to the human body, and are identified as "foreign" by all types of human cells, especially cells of the immune system, noting that Mr. Pritchard's illness is cancer of the immune system. (*Id*).

Dr. Omalu next explains the chemical composition of Dursban insecticides, which include Chlorpyrifos, Xylene,[7] Cumene[8] and Ethyltoluene.[9] (*Id*.) In his view, "[c]hlorpyrifos is an organophosphate compound, which is an irreversible inhibitor of the acetylcholinesterase enzyme."[10]

---

[7] Dr. Omalu explains that "Xylene is a generic term for a group of three aromatic hydrocarbon isomers, essentially benzene derivatives, which encompasses ortho-, meta-, and para- isomers of dimethyl benzene. The o-, m- and p- designations specify to which carbon atoms (of the benzene ring) the two methyl groups are attached. Solvent grade Xylene usually contains a small percentage of ethylbenzene as a contaminant. The synonyms for Xylene include dimethyl benzene; xylol; methyl toluene; 1,4-dimethyl-benzene and Violet 3." (*Dr. Omalu Report* at 3).

[8] According to Dr. Omalu, "Cumene is the common name for isopropulbenzene, an organic compound that is a derivative of benzene. Commercial production of Cumene is carried out through the catalytic alkylation of benzene. Cumene process is an industrial process for developing phenol and acetone from benzene and propylene. The term stems from Cumene (isopropul benzene), the intermediate material during the process." (*Dr. Omalu Report* at 3).

[9] Dr. Omalu states that "Ethyltoluene is a colorless solvent and a derivative of benzene. The synonyms for Ethyltoluene include 1-Ethyl-2-Methylbenzene-2-Ethylbenzene and 2-Methylethylbenzene." (*Dr. Omalu Report* at 3).

[10] "Acetylcholinseterase" is defined as "[t]he cholinesterases that hydrolyze acetylcholine to acetate and choline within the central nervous system and at peripheral neuroeffector junctions (e.g., motor endplates and autonomic ganglia)." STEDMAN'S MEDICAL DICTIONARY at 3400 (27th ed. 2000). An "enzyme" is

> [a] protein that acts as a catalyst to induce chemical changes in other substances, itself remaining apparently unchanged by the process. Enzymes, with the exception of those discovered long ago (e.g., pepsin, emulsin), are generally named by adding -ase to the name of the substrate on which the enzyme acts (e.g., glucosidase), the

(*Dr. Omalu Report* at 3). He further states that "it is common knowledge in medicine that acute and chronic exposure to organophosphate compounds cause multisystem toxic effects," resulting in a litany of diseases and symptoms, several of which Mr. Pritchard has been found to have, including neuropathy, fatigue, bipolar disorder, tremors, difficulty concentrating and liver disorder. (*Id.*). Dr. Omalu opines that these diagnosed diseases and symptoms were caused by Mr. Pritchard's exposure to Dursban. (*Id.*). He also describes the chemical composition of Xylene, Cumene, and Ethyltoluene, concluding that their respective chemical compositions makes them each "benzene derivatives." (*Id.*).

Dr. Omalu then discusses the known risk factors of Non-Hodgkin's Lymphoma, concluding that exposure to agricultural chemicals like Dursban, organophosphate compounds, and benzene derivatives, has been shown to have an increased incidence of Non-Hodgkin's Lymphoma. Specifically, he opines that:

> [a] number of environmental factors have been implicated in the occurrence of Non-Hodgkin's Lymphoma, including infectious agents, chemical exposures, and medical treatments. Many reports have demonstrated an association between exposure to agricultural chemicals like Dursban, which contain compounds like the organophosphate compounds, and an increased incidence of Non-Hodgkin's Lymphoma.
>
> Compounds found in insecticides and agricultural solvents like Dursban, including organosphate compounds and benzene derivatives, induce chronic genotoxic and mutational carcinogenic

---

> substance activated (e.g., hydrogenase), and/or the type of reaction (e.g., oxidoreductase, transferase, hydrolase, lyase, isomerase, ligase or synthetase--these being the six main groups in the Enzyme Nomenclature Recommendations of the International Union of Biochemistry).

STEDMAN'S MEDICAL DICTIONARY at 133650 (27th ed. 2000).

> effects on a broad variety of human cells, which initiate a broad variety of cancers including lymphomas and the type of cancer Mr. Pritchard is suffering from. **Dursban contains an organophosphate compound and at least three benzene derivatives; Xylene, Cumene and Ethyltoluene.** Benzene and other toxic compounds are expected to be contaminants in solvents, which contain benzene derivatives and organic compounds. This is a natural phenomenon observed in chemical behavior of organic compounds and solvents in-vivo and in-vitro.

(*Id.* (emphasis in original)). Dr. Omalu compares his toxicity theory to the numerous opiate derivatives which are found in the blood of heroin abusers despite their having only consumed heroin and not any of the derivatives. (*Id.*). He explains that:

> the human body converts chemical compounds into a myriad of intermediate metabolites, which frequently exhibit novel and independent actions and toxic effects. The cumulative effects of a compound cannot only be determined by the known direct effects of the parent compound alone. The extensive effects of all the metabolites of the compound should also be considered and sometimes, there can be tens and hundreds of metabolites and possible by-products of just one organic parent compound depending on every individual's genetic make-up, proclivities and vulnerabilities.

(*Id.*).

In Dr. Omalu's opinion, Mr. Pritchard's "diseases caused by his chronic exposure to Dursban are irreversible and permanent," they will cause him chronic pain and suffering, severely compromise his quality of life and significantly reduce his life expectancy. (*Id.*).

Dr. Omalu also briefly describes his methodology. He explains:

> [t]he method used to determine causation in this case is a form of the widely accepted method of differential diagnosis. With respect to a causation determination, and in the field of anatomic and clinical pathology, the method would more accurately be termed "differential etiology." This method involves attribution of patient-specific disease etiology to a patient history of substantial exposure to a

> known pathogen based on biologic plausibility, as established by studies or reports linking that pathogen and/or related chemicals to the disease in question and/or related disease processes. This method is generally accepted across disciplines in the field of medicine, and in the discipline of anatomic and clinical pathology in particular.

(*Dr. Omalu Report* at 4). Dr. Omalu initially testified at his deposition and later declared that he had considered and analyzed other potential causes of Mr. Pritchard's Non-Hodgkins Lymphoma, ruling out those other causes that were not sufficient to be a sole cause of the disease. (*Dr. Omalu Deposition* at 168; *Dr. Omalu Declaration* at ¶ 19). He explained that he did not list the other potential causes in his expert report because his role was limited to offering an opinion regarding whether Mr. Pritchard's Dursban exposure caused his NHL. (*Dr. Omalu Deposition* at 170). Dr. Omalu also testified that diabetes may have contributed to Mr. Pritchard's disease but that it was "less likely to have contributed" and that Mr. Pritchard's obesity and body mass index were not highly associated with NHL. (*Id*. at 169-70). He continued that:

> 19. ... The Defense Experts have pointed out that Mr. Pritchard's elevated body mass index and his diabetes mellitus should be considered as factors contributing to his NHL, but they have not opined that these factors constitute a sufficient or sole cause of the disease.
>
> 20. Although obesity and diabetes are both associated with an elevated risk of NHL, the incidence of NHL among persons who are overweight or suffer from diabetes is nevertheless very low, so that these factors cannot be considered sufficient or sole causes of the disease. Rather, as a matter of generally accepted practice in the field of pathology, such factors should be considered as part of the "genetic makeup, proclivities and vulnerabilities" in the context of which the established pathogenicity of the compounds in question operate.

(*Dr. Omalu Declaration* at ¶¶ 19, 20).

As to the studies relied upon by Dr. Omalu, he suggests in his report that "[m]any reports have demonstrated an association between exposure to agricultural chemicals *like* Dursban, which contain compounds *like* the organophosphate compounds, and an increased incidence of Non-Hodgkin's Lymphoma." (*Dr. Omalu Report* at 3 (emphasis added)). He further states that:

> [s]tudies and reports in the medical literature indicate that both benzene-based solvents and organophosphate pesticides are carcinogenic, and are associated with Non-Hodgkin's lymphoma. Although the published literature relating to Chlorpyrifos itself is scant (owing in part to the long latency period for cancers and the relative recency of widespread use of Chlorpyrifos), it has also been found to be associated with cancers including non-Hodgkins lymphoma. These associations, considered in the light of the mechanisms of pathogenicity of the compounds in question, suffice to establish the biologic plausibility of Dursban exposure as a cause of Mr. Pritchard's disease.

(*Id.* at 4). Dr. Omalu did not cite or identify the "studies and reports" upon which he relied in making these statements in his report.

However, after negotiations between counsel, Dr. Omalu's report was supplemented with a series of published articles, including the study by *Won Jin Lee, et al.*, entitled "Cancer Incidence Among Pesticide Applicators Exposed to Chlorpyrifos in the Agricultural Health Study," published at 96 J. Nat. Cancer Inst. 1781 (2004) (the "2004 Lee Study").[11] Dr. Omalu testified directly regarding the 2004 Lee Study, (*Dr. Omalu Deposition* at 81-83), and later asserted "[t]he 2004 Lee Study is an important part of the medical/scientific literature on which I relied in forming the opinion expressed in my Report" and "the 2004 Lee Study strongly supports a conclusion that high-level

---

[11] The Court notes that the entire series of articles were not produced by the parties to the Court. However, the full list is briefly summarized in Dr. Grufferman's report. (*See* Docket No. 128-4, Exhibit 8, *Dr. Grufferman Report*).

exposure to chlorpyrifos is associated with an increased risk of NHL." (*Dr. Omalu Declaration* at ¶¶ 5, 14). In support, he states that "the 2004 Lee Study found a 1.6-fold increased incidence of NHL among pesticide applicators within the highest quartile of chlorpyrifos exposure (measured against a reference population of pesticide applicators who used other pesticides that did not contain chlorpyrifos but may have contained other organophosphates)." (*Id.* at ¶ 8). Further, Dr. Omalu disagrees with the theory that "the 2004 Lee Study does not support a finding of association between chlorpyrifos exposure and NHL even for highly-exposed applicators" "[b]ecause a part of the 95% confidence interval around the foregoing 1.6 relative risk corresponds to a relative risk less than 1.0." (*Id*. at ¶ 9). Instead, Dr. Omalu interprets and recalculates the findings in the 2004 Lee Study, finding that "an 80% confidence interval for the highly-exposed applicators in the 2004 Lee Study spans a relative risk range for NHL from slightly above 1.0 to slightly above 2.5." (*Id*. at ¶ 12). Dr. Omalu concludes that "this means that there is a 90% probability that the relative risk within the population studied is greater than 1.0."[12] (*Id*.).

Finally, Dr. Omalu states that "[o]ther studies on which I have relied establish the general carcinogenicity of benzene-related solvents (such as those found in Dursban), and also an association between organophosphate pesticides in general and NHL." (*Id.* at ¶ 17). Again, he does not identify these studies.

2. Defense Experts

---

[12] At oral argument, Plaintiffs' counsel argued that this calculation was done using "high school math." (Docket No. 152 at 96-102). He also requested an opportunity to present same to the Court in conjunction with his supplemental brief, but failed to do so. (Docket No. 152 at 181-84). As a consequence, there is no record of the method used by Dr. Omalu in making the actual calculations referenced in his declaration.

Defendants have submitted three rebuttal reports in opposition to Dr. Omalu's reports. Plaintiffs have not challenged the admissibility of the defense experts' opinions at this juncture. Therefore, the Court only briefly addresses the defense experts' qualifications and opinions.

Dr. Seymour Grufferman is proffered as an expert in epidemiology. (Docket No. 128-4, Exhibit 8). He obtained his M.D. from State University of New York Upstate Medical Center in 1964, and the following epidemiology degrees, an M.P.H. in 1968, M.S. in 1974, and Dr.P.H. in 1979, from Harvard School of Public Health. His has significant clinical and academic experience in the field of epidemiology and has conducted a number of studies and published a series of articles and texts in that field. (*Id.*). In his rebuttal report, Dr. Grufferman reviews the pertinent literature on NHL and chlorpyrifos, concluding that no epidemiological study has shown a statistically significant increased risk in NHL as a result of exposure to chlorpyrifos. (*Id.*). He thoroughly criticizes Dr. Omalu's opinion that such an association exists, and, in a later declaration, criticizes Dr. Omalu's declaration and his interpretation of the 2004 Lee Study. (*Id.*; Docket No. 149-1, Exhibit 42, *October 29, 2009 Declaration of Dr. Seymour Grufferman*).

Dr. Michael Greenberg is proffered as an expert in toxicology. (Docket No. 128-3, Exhibit 7). He obtained his M.D. from Temple University School of Medicine in 1976, an M.P.H. with specialization in Occupational Medicine from the Medical College of Wisconsin in 1994, and an M.S. in Forensic Toxicology from the University of Florida in 2008. (*Id.*). In his rebuttal report, Dr. Greenberg criticizes Dr. Omalu's opinions regarding the effects of chlorpyrifos, xylene, cumene, and ethyltoluene. (*Id.*). He further contends that Dr. Omalu's opinions are flawed and are contrary to well established principles of toxicology. (*Id.*).

Dr. Marshall Lichtman is proffered as an expert in hematology. (Docket No. 128-5, Exhibit

10). He obtained his M.D. from the University of Buffalo School of Medicine in 1960. (*Id.*). He is presently a professor of medicine in hematology/oncology, biochemistry and biophysics at the University of Rochester Medical Center and a senior physician at Strong Memorial Hospital in Rochester, New York. (*Id.*). He has significant relevant clinical and academic experience in hematology and oncology. (*Id.*). Like the other defense experts, his review of the pertinent literature does not demonstrate an association between chlorpyrifos exposure and NHL. (*Id.*). He also reviews Mr. Pritchard's medical background and identifies several other potential risk factors for Mr. Pritchard's NHL, including, alcoholism, diabetes mellitus, and an elevated body-mass-index. (*Id.*).

C. Challenge to Dr. Omalu's Qualifications

Defendants first challenge Dr. Omalu's qualifications to render his proffered opinions. They argue that he is not qualified to opine as to the medical cause of Mr. Pritchard's disease because he is not an oncologist or a hemopathologist and has never treated patients with NHL or patients that have been exposed to chlorpyrifos. (Docket No. 128). They complain that Dr. Omalu's opinions should be excluded because this litigation is his "first venture in evaluating whether a chemical can cause, and specifically did cause, NHL and/or DLBCL NOS in a human." (Docket No. 128 at 14). In response, Plaintiffs maintain that Dr. Omalu's qualifications are sufficient because he is a pathologist and his opinions regarding the causal etiology of Mr. Pritchard's disease are "squarely within the core of his specialized field." (Docket No. 135 at 4-5).

"Qualification requires 'that the witness possess specialized expertise.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (quoting *Schneider*, 320 F.3d at 404). There is a liberal policy of admissibility and the Court of Appeals has held that a "broad range of knowledge, skills, and training qualify an expert." *Id.* (quoting *Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-42 (3d

Cir.1994)). "This liberal policy of admissibility extends to the substantive as well as the formal qualifications of experts." *Pineda*, 520 F.3d at 244 (citing *Paoli*, 35 F.3d at 741). Further, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." *Id*. (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir.1996)); *see also Kannankeril*, 128 F.3d 802 at 809 ("We reject [defendant's] suggestion that [the doctor] must be an expert in Dursban to provide expert testimony on the causation of [plaintiff's] injury."). "If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." *Kannankeril*, 128 F.3d at 809 (citing *Paoli*, 35 F.3d at 741).

In this Court's estimation, Dr. Omalu's general qualifications are sufficient to withstand *Daubert* scrutiny. He has substantial experience as a pathologist, four separate board certifications in that field, and, a Master's degree in epidemiology; thus, he is qualified to render an opinion about the pathological etiology of Mr. Pritchard's disease. That Dr. Omalu is also not an oncologist or hemopathologist, appropriate specialties in Defendants' view, and has not previously treated and/or diagnosed patients with NHL, does not preclude him from testifying as an expert in this matter. These factors more properly bear on Dr. Omalu's credibility and the weight of his testimony rather than its admissibility. *See Kannankeril*, 128 F.3d at 809. Accordingly, Defendants' motion to exclude, to the extent they rely on a lack of qualifications, is denied.

D. Challenge to the Reliability of Dr. Omalu's Proffered Testimony

Defendants next assail the reliability of Dr. Omalu's proffered testimony. They argue that his opinions are deficient in that they do not reliably establish general causation, i.e., that exposure

to chlorpyrifos can cause NHL, or specific causation, i.e., that Mr. Pritchard's exposure to Dursban caused his NHL. (Docket No. 128). Plaintiffs counter each of these arguments, taking the position that Dr. Omalu's proffered testimony is admissible under *Daubert* and Rule 702. (Docket No. 135).

"An expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Paoli*, 35 F.3d at 742; *see also Pineda*, 520 F.3d at 244 (quoting same). The Court of Appeals has outlined the following factors for consideration by the trial court in assessing the reliability of a particular methodology:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Pineda, 520 F.3d at 247-48 (citing *Paoli*, 35 F.3d at 742 n.8). These factors, however, "are neither exhaustive nor applicable in every case." *Kannankeril*, 128 F.3d at 806-07.

> [T]he reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia*. However, not only must each stage of the expert's testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules.

Heller, 167 F.3d at 155.

"Courts in toxic tort cases often separate the causation inquiry into general causation-whether the substance is capable of causing the observed harm in general-and specific causation-whether the substance actually caused the harm a particular individual suffered." *Perry v. Novartis Pharmaceuticals Corp.*, 564 F.Supp.2d 452, 463 (E.D.Pa. 2008). But,

> the expert's journey from general causation to specific causation need not be just a two-step process. So long as, taken together, the experts are able to draw a chain of scientifically-reliable causal links that meets plaintiffs' requirements under the substantive tort law, the evidence is admissible and it will be left to the jury to establish the relative credibility of the parties' competing experts. Where, however, the expert reports leave wide, unexplained gaps in the causal chain, the evidence is not helpful to the trier of fact and must be excluded.

Perry, 564 F.Supp.2d at 464. The Court finds it helpful to first address general causation and then specific causation.

1. General Causation

General causation is often established in a toxic tort case through the use of epidemiological studies. "Epidemiology is 'the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease.'" *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F.Supp.2d 434, 532 (W.D.Pa. 2003)(quoting *Conde v. Velsicol Chem. Corp.*, 804 F.Supp. 972, 1025-26 (S.D.Ohio 1992)); *see also Perry*, 564 F.Supp.2d at 465 (quoting *Soldo*). "Epidemiological studies examine the pattern of disease in human populations," *General Elec. Co. v. Joiner*, 522 U.S. 136, 144 n.2 (1997), and, more specifically, "[e]pidemiologic evidence identifies agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent," Federal Judicial Center, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, *Reference Guide on Epidemiology* at 335-36 (2d ed. 2000). The United States Court of Appeals for the Third Circuit has recognized that "[t]he reliability of expert testimony founded on reasoning from epidemiological data is generally a fit subject for judicial notice; epidemiology is a well-established branch of science and

medicine, and epidemiological evidence has been accepted in numerous cases." *DeLuca v. Merrell Dow Pharmacueticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). The parties agree that general causation can be established through the use of such studies. *See also* REFERENCE MANUAL at 336 ("Epidemiology focuses on the question of general causation (i.e., is the agent capable of causing the disease?) rather than specific causation (i.e., did it cause disease in a particular individual?)"). Indeed, Dr. Omalu states in his report that a differential diagnosis or differential etiology relies upon or is "based on biologic plausibility, *as established by studies or reports linking that pathogen and/or related chemicals to the disease in question and/or related disease processes.*" (*Dr. Omalu Report* at 4 (emphasis added)). However, the parties disagree regarding the need for and use of epidemiological studies by Dr. Omalu in this case.

Defendants challenge Dr. Omalu's general causation opinion that exposure to Dursban can cause NHL because his opinions do not rely on statistically significant epidemiological studies, specifically that Dr. Omalu did not rely on an epidemiological study showing an association between chlorpyrifos and NHL with a relative risk greater than 2.0. (Docket No. 128 at 19-28). They further argue that Dr. Omalu's opinion is also unreliable because he ignores published epidemiology studies which show a lack of an association or an inverse relationship between chlorpyrifos and NHL. (*Id.* at 19-20). Plaintiffs contend that under the Third Circuit Court of Appeals' decision in *Heller* they are not required to present statistically significant studies which demonstrate an association between chlorpyrifos and NHL in order to demonstrate general causation. (Docket No. 135 at 5-7). Alternatively, they argue that Dr. Omalu's opinion is supported by published epidemiological studies, focusing primarily on the 2004 Lee Study and Dr. Omalu's interpretation of same. (*Id.* at 7-11).

The law regarding the need for epidemiological studies is not clearly established, although

caselaw from the Court of Appeals for the Third Circuit and district courts within the Third Circuit suggest certain principles of law which can be applied to the case at bar. As is discussed in further detail below, the caselaw suggests that this Court should avoid adopting *per se* rules of admissibility but should consider the following as factors in determining the reliability of an expert's opinion on general causation: whether the expert relied on epidemiological studies; whether the expert ignored or sufficiently addressed epidemiological studies which contradicted his hypothesis, explaining the discrepancy between his hypothesis and that of the authors; and, whether the findings set forth in the studies are statistically significant.

In *Heller*, our Court of Appeals declined to adopt a bright-line rule requiring a general causation opinion to be supported by published, peer-reviewed studies finding an association between a chemical agent and an illness. *Heller*, 167 F.3d at 155. Specifically, the Court of Appeals held that a medical expert does not always need to "cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness." *Id.* In so holding, the Court of Appeals recognized that the lack of such studies did not render the expert's opinion unreliable in that case because the expert had also conducted a reliable differential diagnosis[13] and opined that the temporal relationship between the plaintiff's exposure to the chemical and the onset of the plaintiff's symptoms strongly supported causation. *Id*. at 155-56. Thus, *Heller* stands for the proposition that epidemiology studies are not *per se* required, and may not be needed, but only if an expert offers a reliable causation opinion through the use of some other valid scientific methodology. Moreover, the Court of Appeals in *Heller* explicitly held that a district court *may properly consider*

13

The Court notes that the method of differential diagnosis and reliability of the differential diagnosis conducted by Dr. Omalu in this case are discussed in detail in section (III)(D)(2) *infra*.

the fact that an expert relied on few, if any, studies linking exposure to a particular illness in evaluating whether the expert had "good grounds" to arrive at his conclusions. *Id*. at 158.

In addition, *Heller* considered an expert's causation opinion based on a record that lacked any epidemiology studies. Therefore, the Court of Appeals did not directly address the admissibility of expert testimony that fails to account for published epidemiology studies with conclusions contrary to the expert's opinion that were presented by the opposition. This issue, on the other hand, was addressed in *Perry v. Novartis Pharmaceuticals Corp.*, 564 F.Supp.2d 452 (E.D.Pa. 2008). Like the instant case, *Perry* also dealt with a plaintiff who was diagnosed with NHL and claimed that exposure to a chemical caused the disease. In *Perry*, the district court recognized that "while an expert's conclusions reached on the basis of other studies could be sufficiently reliable where no epidemiological studies have been conducted, no reliable scientific approach can simply ignore the epidemiology that exists." *Perry*, 564 F.Supp.2d at 465. While this passage in *Perry* is seemingly drafted in absolute terms, when read in conjunction with *Heller*, it can reasonably be inferred that this Court should consider whether an expert such as Dr. Omalu addressed contrary epidemiological studies when developing his opinions.

Many epidemiology studies measure the strength of a causal association between an agent and a disease by calculating the relative risk. REF. MAN., 2d ed. at 376. "The higher the relative risk, the greater chance that a relationship is causal." *Id*. The relative risk factor determined in epidemiology studies can be adapted to the civil preponderance of the evidence, or more likely than not, standard. *Id*. at 383.

> The threshold for concluding that an agent was more likely than not the cause of an individual's disease is a relative risk greater than 2.0. ... When the relative risk reaches 2.0, the agent is responsible for an

> equal number of cases of disease as all other background causes. Thus, a relative risk of 2.0 ... implies a 50% likelihood that an exposed individual's disease was caused by the agent. A relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent.

Id. at 384. Some courts have refused to consider epidemiology studies with less than a relative risk of 2.0 as supporting an association between a chemical agent and a disease. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1320 (9th Cir.), *cert denied*, 516 U.S. 869, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995); *see also In re W.R. Grace & Co.*, 355 B.R. 462, 482 (D. Del. Bankr. 2006)(adopting 2.0 relative risk standard). Other courts have permitted the use of studies showing less than a 2.0 relative risk in support of a causation opinion. *See In re Joint E. & S. Dist. Asbestos Litig.*, 964 F.2d 92, 97 (2d Cir. 1992). Our Court of Appeals has not resolved this issue. *See DeLuca by DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941, 958-59 (3d Cir. 1990)(commenting that "[i]f New Jersey law requires the DeLucas to show that it is more likely than not that Bendectin caused Amy DeLuca's birth defects, and they are forced to rely solely on Dr. Done's epidemiological analysis in order to avoid summary judgment, the relative risk of limb reduction defects arising from the epidemiological data Done relies upon will, at a minimum, have to exceed '2'"). However, given the Court of Appeals' holdings in *Heller*, *Paoli* and *Kannankeril*, which favor a flexible *Daubert* inquiry rather than bright-line rules, this Court believes that the approach taken in *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp.2d 584, 606 (D.N.J. 2002) is best used. In *Magistrini*, the district court explained that "a relative risk of 2.0 is not so much a password to a finding of causation as one piece of evidence, among others for the court to consider in determining whether an expert has employed a sound methodology in reaching his or her conclusion." *Magistrini*, 180

F.Supp.2d at 606 (quoting *Landrigan v. Celotex Corp.*, 127 N.J. 404, 419, 605 A.2d 1079, 1087 (1992)). Therefore, a relative risk of 2.0 is not dispositive of the reliability of an expert's opinion relying on an epidemiological study, but it is a factor, among others, which the Court is to consider in its evaluation.

Other factors which the Court should consider include the confidence interval and range of relative risk values set forth in an epidemiological study. As noted in *Soldo*,

> [a] particular epidemiologic study's measurement of relative risk has no meaning by itself but must be interpreted in conjunction with its statistical degree of confidence. Relative risk is always expressed with "confidence intervals" that indicate a range of relative risk values in which the "true" relative risk is very likely to fall. A confidence interval that includes 1.0 means that the relative risk estimate in a particular study is not statistically significant. Relative risk is the ratio of the incidence of disease in exposed individuals to the incidence in unexposed individuals. A relative risk of 1.0 means that the incidence in each group is the same, i.e., the exposure has no association with the disease. A relative risk significantly below 1.0 means that the exposure is associated with the absence of the disease, whereas a relative risk significantly above 1.0 means that exposure is associated with an increased risk of the disease.

Soldo, 244 F.Supp.2d at 449-50 (W.D.Pa. 2003)(citing REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (1st ed. 1994))(internal citations omitted). Further, the Court should also consider whether the authors of the study found the association to be statistically significant and, where the authors found an association to not be statistically significant, an opinion may be unreliable. *See Joiner*, 522 U.S. at 518-19.

With this backdrop, the Court now turns to Dr. Omalu's general causation opinions and the parties' arguments.

Plaintiffs first suggest that because Dr. Omalu states in his report that the published literature

demonstrates an association between exposure to chlorpyrifos and NHL, without any citation or supporting authority, and the defense experts disagree with this opinion, they have sufficiently raised a jury issue regarding whether there is an association between chlorpyrifos and NHL. (Docket No. 135 at 5-7). This Court disagrees. Dr. Omalu's bare assertion of an association, which is challenged by Defendants, is not reliable. *See Heller*, 167 F.3d at 155 (citing *Paoli*, 35 F.3d at 743-45)("the reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia*."). Moreover, it is the Plaintiffs' burden to demonstrate that Dr. Omalu's opinion is based on "good grounds" and not the Defendants' burden to refute same. *See Kannankeril*, 128 F.3d at 807 (the plaintiffs' "needed to demonstrate by a preponderance of evidence only that [the expert's] opinion was based on 'good grounds.'").

Likewise, Dr. Omalu's opinion that organophosphate pesticides and benzene derivatives are toxic and exposure to same is associated with NHL, (*Dr. Omalu Report* at 3), is also unsupported with any specific "studies" and, thus, unreliable.[14] Further, Plaintiffs' reliance on *Kannankeril* in support of the proposition that organophosphates are generally toxic and associated with an increased risk of NHL is misplaced. First, Plaintiffs conflate legal argument with science. Dr. Omalu has not stated that he relied on *Kannankeril* in rendering his opinion and his doing so would clearly be unreliable. Second, while the plaintiff in *Kannankeril* was exposed to Dursban, the plaintiff alleged only that she suffered from cognitive impairments as a result of her exposure and there were no

---

[14] The Court notes that Dr. Omalu's more general opinion that "[m]any reports have demonstrated an association between exposure to agricultural chemicals *like* Dursban, which contain compounds *like* the organophosphate compounds, and an increased incidence of Non-Hodgkin's Lymphoma" shows a lack of "fit." (*Dr. Omalu Report* at 3 (emphasis added)).

allegations that her exposure caused any form of cancer, let alone NHL. *Kannankeril*, 128 F.3d 802. The only epidemiology study upon which Dr. Omalu has testified and declared that he specifically relied was the 2004 Lee Study, to which the Court now turns.

The full title of the 2004 Lee Study is "Cancer Incidence Among Pesticide Applicators Exposed to Chlorpyrifos in the Agricultural Health Study." (*2004 Lee Study*, Docket No. 135-3). The Agricultural Health Study was the "largest epidemiologic study of pesticide applicators exposed to chlorpyrifos," analyzing 54,383 pesticide applicators and their spouses in Iowa and North Carolina from when the applicators were enrolled (1993-1997) until December 31, 2001. (*2004 Lee Study* at 2, 7). The study collected data regarding the applicators' exposure to and use of certain pesticides, including application methods, use of protective equipment, and other environmental and occupational factors. (*Id.*). The authors of the 2004 Lee Study analyzed the data collected from this study. At the outset, they noted that "[t]here is little epidemiologic evidence of an association between chlorpyrifos exposure and human cancer, and most experimental studies have provided little or no evidence that chlorpyrifos has mutagenic or carcinogenic effects in humans."[15] (*Id.*). However, after analyzing the data in the Agricultural Health Study, the authors found a "statistically

---

[15] The 2004 Lee Study also notes that "[a] case-control study reported increased risk of non-Hodgin['s] Lymphoma among male farmers exposed to chlorpyrifos in the United States, although that result was based on only seven cases." *2004 Lee Study* at 1. This note references a study by *Waddell BL, et al*, "Agricultural use of organophosphate pesticides and the risk of non-Hodgkin's lymphoma among male farmers (United States)," Cancer Causes Control 2001; 12:509-517. *Lee Study* at 8. While Plaintiffs' counsel made much of this note and the reference to the Waddell Study during oral argument, there is no evidence of record that Dr. Omalu relied on this study, absent a reference to the same in Dr. Grufferman's rebuttal report, which briefly summarized the studies which were later supplemented to support Dr. Omalu's report. Plaintiffs never produced the study to the Court and, more importantly, Dr. Omalu has offered no opinion regarding the Waddell Study in any portion of the present record.

significant trend of increasing risk of lung cancer, but not of any other cancer examined, with increasing chlorpyrifos exposure." (*Id*. at 5). They specifically investigated exposure to chlorpyrifos and incidences of NHL. (*Id*.).

Dr. Omalu points to a single statistic in the 2004 Lee Study in support of his general causation opinion that there is an association between chlorpyrifos and NHL. (*Dr. Omalu Declaration*). The authors of the 2004 Lee Study found a 1.6-fold increase in incidence of NHL in the pesticide applicators within the highest quartile of chlorpyrifos exposure. (*2004 Lee Study* at 5, table 3). Specifically, they found a relative risk of 1.6, with a 95% confidence interval ranging from 0.74 to 3.53. (*Id*.). As noted, the authors of the 2004 Lee Study did not find these results to be statistically significant. However, in his declaration, Dr. Omalu interprets the findings in the 2004 Lee Study by lowering the confidence interval to 80%, which he posits would result in "a relative risk range for NHL from slightly above 1.0 to slightly above 2.5," concluding that "this means that there is a 90% probability that the relative risk within the population studied is greater than 1.0." (*Omalu Declaration* at ¶ 12). He further declares that "the authors of the 2004 Lee Study themselves endorse the probative value of a finding of elevated risk with less than a 95% confidence level when they point out that 'this analysis had a 90% statistical power to detect a 1.5-fold increase in lung cancer incidence.'" (*Omalu Declaration* at ¶ 11). Dr. Omalu also assumes that Mr. Pritchard would be in the highest quartile of chlorpyrifos exposure based on his allegations in this case. (*Omalu Declaration* at ¶ 15, 16).

Plaintiffs argue that Dr. Omalu's interpretation of the 2004 Lee Study is sufficient to demonstrate a statistically significant association between chlorpyrifos exposure and NHL. (Docket No. 135 at 7-9). This Court again disagrees. First, the authors of the 2004 Lee Study did not find

a statistically significant association and the author's determination renders Dr. Omalu's reliance on same unreliable. *See Joiner*, 522 U.S. at 518-19. Second, although Plaintiffs' counsel attempted to explain how the calculations were made during oral argument, there is no evidence of record explaining the method that Dr. Omalu used. (Docket No. 152 at 96-102; *see also* n.12 *supra*). Therefore, the Court simply cannot evaluate whether the methodology used is reliable in light of the factors suggested by the Third Circuit. *Pineda*, 520 F.3d at 247-48 (citing *Paoli*, 35 F.3d at 742 n.8)(listing eight (8) suggested non-exhaustive factors to consider in determining reliability of an expert's method). Third, Plaintiffs' counsel's involvement in drafting the declaration further undermines the reliability of the opinions contained therein. Plaintiffs' counsel admitted that he drafted the declaration, after discussing the content of same with Dr. Omalu, who then signed it without any changes. (Docket No. 142 at 76). The declaration contains repeated references to legal terms such as "probative value," and, as noted, Plaintiffs' counsel attempted to explain the mathematical computations to the Court during the motion hearing. (Docket No. 152 at 96-102). Therefore, as the methods used by Dr. Omalu in his interpretation of the 2004 Lee Study are not reliable, the Court will not consider same as establishing a statistically significant association between chlorpyrifos exposure and NHL.

Dr. Omalu also never addressed two studies raised by Defendants and their experts which refute his opinion that exposure to chlorpyrifos can cause NHL. A mortality study by *Lee, et al.*, titled "Mortality among Pesticide Applicators Exposed to Chlorpyrifos in the Agricultural Health Study," found a relative risk of .64, with a 95% confidence interval ranging from .29-1.39, that the cause of death of pesticide applicators in the Agricultural Health Study was NHL. (Docket No. 128-9, Exhibit 35, *2007 Lee Study* at 3). In addition, a study by *Colt et al.*, titled "Residential Insecticide

Use and Risk of Non-Hodgkin's Lymphoma," (Docket No. 128-9, Exhibit 36, 2006 Colt Study at 4), did not find an increased risk in NHL among people whose homes were treated with chlorpyrifos, but did find an increased risk among those whose homes were treated with chlordane. Despite the fact that both the 2007 Lee Study and the 2006 Colt Study were reviewed by Dr. Omalu, as Plaintiffs included both as a part of their supplement to his expert report, Dr. Omalu offers no explanation regarding the studies' findings and his hypothesis in this case.

In sum, Dr. Omalu's general causation opinion that exposure to Dursban is associated with an increased incidence of NHL is unreliable. Plaintiffs cannot rely on Dr. Omalu's bare assertions that "studies" show that there is an association between chlorpyrifos, benzene derivatives, or organophosphates and NHL. His opinion as to chlorpyrifos exposure is based on a single epidemiological study, and the authors of the study found only a weak association which was not statistically significant. Dr. Omalu also failed to address contrary studies which were raised by Defendants or adequately explain the differences between his opinions and the findings of those studies. Accordingly, for all of these reasons, Dr. Omalu's opinion on general causation is unreliable.

2. Specific Causation

The Court next turns to the parties' respective positions on Dr. Omalu's specific causation opinions that Mr. Pritchard's exposure to Dursban caused his NHL. Defendants contend that Dr. Omalu's differential diagnosis is not reliable, while Plaintiffs maintain that it is sufficient.

The use of differential diagnosis has been approved as an appropriate scientific method in the Third Circuit. Differential diagnosis is "the basic method of internal medicine," *Paoli*, 35 F.3d at 755, and is "a technique that involves assessing causation with respect to a particular individual," *Kannankeril*, 128 F.3d at 807. "Differential diagnosis, or differential etiology, is a standard scientific

technique which identifies the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Magistrini*, 180 F.Supp.2d at 609; *Heller*, 167 F.3d at 154-55 (quoting *Paoli*, 35 F.3d at 742 n. 8)("differential diagnosis 'consists of a testable hypothesis,' has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context."). Although the use of differential diagnosis is generally accepted, an expert's use of same must still be evaluated in order to ensure that the methods employed are reliable. *See Heller*, 167 F.3d at 155 (citing *Paoli*, 35 F.3d at 743-45)("the reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia*."); *see also Soldo*, 244 F.Supp.2d at 551 ("as *Heller* also demonstrates, the mere statement by an expert that he or she applied differential diagnosis in determining causation does not *ipso facto* make that application scientifically reliable or admissible."). However, that an expert used this technique in order "'to testify to a novel conclusion' is not sufficient grounds for excluding his testimony." *Heller*, 167 F.3d at 156 (quoting *Paoli*, 35 F.3d at 759 n.27).

Defendants contend that Dr. Omalu's differential diagnosis is unreliable because of his limited review of Mr. Pritchard's case, primarily faulting Dr. Omalu for not physically examining Mr. Pritchard, reviewing all of his medical records and relying, in part, on an oral medical history transmitted by Mr. Pritchard to Dr. Emilio Navarro. (*See generally* Docket No. 128).

In *Paoli*, the Court of Appeals held that "performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable." *Paoli*, 35 F.3d at 758-59; *see also Heller*, 167 F.3d at 156 (suggesting that an

expert conducted a reliable differential diagnosis by "ordering standard laboratory tests, physically examining the plaintiff, taking medical histories, and considering alternative causes of the plaintiff's illness."). The Court of Appeals has also cautioned that "there will be some cases in which a physician can offer a reliable differential diagnosis without examining the patient, looking at medical records, taking a medical history, and performing laboratory tests." *Paoli*, 35 F.3d at 762; *see also Kannankeril*, 128 F.3d at 807 ("Depending on the medical condition at issue and on the clinical information already available, a physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available. In fact, it is perfectly acceptable, in arriving at a diagnosis, for a physician to rely on examinations and tests performed by other medical practitioners."). In light of this precedent, Dr. Omalu's proffered testimony cannot be excluded solely based on his limited review of Mr. Pritchard's medical background. However, as discussed in further detail below, his admitted failure to review all of Mr. Pritchard's medical records, his discovery responses, his deposition testimony, his application records, or any other evidence regarding Mr. Pritchard's exposure to chlorpyrifos or other pesticides, leaves his opinions unsupported and renders his differential diagnosis methodology unreliable. Thus, his opinions must be excluded because they are not based on "good grounds."

In *Heller*, the Court of Appeals held that it is an error of law to exclude expert testimony on the basis that an expert failed to rule out *all* alternative possible causes when conducting a differential diagnosis. *See Heller*, 167 F.3d at 156. However, the Court of Appeals also recognized that an expert must rule out obvious alternative causes and address the plausible alternative causes proposed by a defendant, explaining why the initial opinions remain reliable in light of the proposed alternative causes. *Heller*, 167 F.3d at 156 ("only where a defendant points to a plausible alternative

cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.")(internal quotation omitted); *Kannankeril*, 128 F.3d at 808 ("In attacking the differential diagnosis performed by the plaintiff's expert, the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions. It then becomes necessary for the plaintiff's expert to offer a good explanation as to why his or her conclusion remains reliable."). Further, this Court must consider the expert's responses to the Defendants' proposed alternative causation theories in evaluating whether he had "good grounds" for the conclusion he reached. *See Heller*, 167 F.3d at 158.

Dr. Omalu's initial report is conclusory, stating that he used the method of differential diagnosis or differential etiology. (*Dr. Omalu Report*). It does not mention any alternative causes that he considered. (*Id.*). During Dr. Omalu's deposition and in their rebuttal expert reports, Defendants raised a number of potential alternative causes.[16] The potential risk factors include the following: Mr. Pritchard's exposure to pesticides other than Dursban, his diabetes, an elevated body-mass-index which indicates that he is overweight, his family medical history, exposure to benzene through second hand smoke and that the cause of NHL is idiopathic or unknown. In this Court's estimation, and for the reasons set forth below, Dr. Omalu's responses to the Defendants' potential alternative causes are not sufficient under *Heller* and *Kannankeril*.

When confronted at his deposition, Dr. Omalu admitted that he did not perform an "exhaustive" differential diagnosis and that doing so would have required a review of all of Mr.

---

[16] In their initial briefing, Defendants made much of Dr. Omalu's seemingly contradictory statements during his deposition regarding whether differential diagnosis is a process of inclusion versus a process of exclusion. (Docket No. 128). Given the Court's holding, this argument need not be specifically addressed.

Pritchard's medical records. (*Omalu Deposition* at 170). Specifically, he engaged in the following exchange with defense counsel.

> Q: Can you just list for me the things that you considered and excluded as a cause, other than Dursban, of Mr. Pritchard's diffuse large B-cell lymphoma?
>
> A: If you notice, I did not list... the specific question I was asked was did Dursban exposure contribute to his non-Hodgkin's lymphoma, which I addressed. And if you want me to provide you an exhaustive list – this was why I didn't ask for medical records – if you want me to provide you with an exhaustive differential diagnosis list, I'll ask you to provide me with all his medical records.
>
> Q: So to do that you would need the medical records?
>
> A: Yes. But the question here, the prevailing medical-legal question here is did Dursban contribute to [Mr. Pritchard's] development of non-Hodgkin's and this other syndrome he's suffering from? Yes.

(*Omalu Deposition* at 170). The fact that Dr. Omalu admits that he did not have the materials necessary to perform a complete differential diagnosis undermines the reliability of his opinions.

Dr. Omalu also admitted that he had no knowledge of Mr. Pritchard's exposure to pesticides other than Dursban and, therefore, could not have excluded Mr. Pritchard's exposure to these pesticides as a potential sole cause of his NHL. (*Dr. Omalu Deposition* at 45-55). As a glaring example of this lack of knowledge of the facts of this case, Dr. Omalu was first confronted with the information that Mr. Pritchard was exposed to chlordane, a chemical which Dr. Omalu believes has been associated with incidences of NHL, during his deposition.[17] (*Dr. Omalu Deposition* at 160-61).

---

[17] Chlordane is a chemical that was previously used as an ingredient in pesticides. (*2006 Colt Study* at 1, 4). Its use was banned by the United States government in 1988. (*Id.*). The authors of the 2006 Colt Study determined that "residential use of chlordane termiticides increases residents'

Since Dr. Omalu had no awareness of Mr. Pritchard's exposure to pesticides other than Dursban, he did not conduct a thorough differential diagnosis. *See Heller*, 167 F.3d at 156 (holding that an expert must rule out "obvious" alternative causes); *see also Soldo*, 244 F.Supp.2d at 551 (citing *Heller*, 167 F.3d at 156)(interpreting *Heller* as requiring a district court to "explore the alternative hypotheses posited by defendant's experts and plaintiff's experts' response thereto. If the alternative hypotheses are 'plausible,' then plaintiff's experts must show that they have been reliably ruled out.").

Further, Dr. Omalu did not attempt to rule out that Mr. Pritchard's NHL is the result of an idiopathic or unknown cause despite the fact that the general cause of NHL is unknown. As one district court has noted, "[s]tanding alone, the presence of a known risk factor is not sufficient basis for ruling out idiopathic origin in a particular case, particularly where most cases of the disease have no known cause." *Perry*, 564 F.Supp.2d at 470. Likewise, Dr. Omalu's conclusion that Mr. Pritchard's NHL is not idiopathic because he determined that his disease was caused by exposure to Dursban, (*see* Docket No. 135-4, *Dr. Omalu Deposition* at 218-19), is not a sufficient explanation, as it is merely a conclusion unsupported by any scientific theory or method.

That Dr. Omalu did respond to several of the Defendants' proffered causation theories during his deposition and in his declaration, particularly obesity and diabetes, does not save the glaring omissions in his methodology.

E. Challenge to the "Fit" of Dr. Omalu's Proffered Testimony to the Facts of this Case

Having concluded that the methodology used by Dr. Omalu is not reliable and finding that his proffered testimony must be excluded, the Court need not address the "fit" issue. However, even

---

NHL risk." (*Id*. at 6). The EPA has classified chlordane as Group 2: Probable Human Carcinogen. (Docket No. 128-9, Exhibit 24, *List of Chemicals Evaluated for Carcinogenic Potential* at 2).

if the Court had found Dr. Omalu's methodology to be reliable, his proffered opinions would be excluded as they do not "fit" this case.

"Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404. Moreover, "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id*. (citing *Daubert*, 509 U.S. at 591-92). The requirement of "fit" "depends in part on the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Paoli*, at 743. Further, "even if the data ... and the methodology (i.e., the differential diagnosis) were reliable," the conclusions reached by the expert must reliably flow from the data and methodology. *Heller*, 167 F.3d at 159.

For many of the reasons previously discussed, the conclusion reached by Dr. Omalu does not reliably flow from the data and methodology used in this case. For one, the data is flawed as Dr. Omalu failed to properly consider all of the relevant materials, specifically, Mr. Pritchard's medical records, his pesticide application records as well as any information relevant to Mr. Pritchard's exposure to Dursban or other pesticides. Thus, Dr. Omalu's opinions flowing from an incomplete set of facts are speculative.[18] His opinions are also not grounded in science as he has not presented

---

[18] The United States Court of Appeals for the Third Circuit has held that "[a]n expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000); *see also Soldo,* 244 F.Supp.2d at 559 (quoting *Daubert*, 509 U.S. at 589-90)("As used in Rule 702, 'the adjective "scientific" implies a grounding in the method and procedures of science,' and 'the word "knowledge" connotes more than subjective belief or unsupported speculation."). Likewise, under Pennsylvania law, an expert on medical causation must testify to a "reasonable degree of medical certainty," a standard which cannot be met if the expert testimony is based on speculation. *Griffin*

any statistically significant evidence showing an association between any of the chemical agents at issue and NHL, much less DBLCL NOS. Moreover, his more general opinion that "[m]any reports have demonstrated an association between exposure to agricultural chemicals *like* Dursban, which contain compounds *like* the organophosphate compounds, and an increased incidence of Non-Hodgkin's Lymphoma" does not "fit" with the conclusion that Mr. Pritchard's exposure to Dursban actually caused his NHL in this case. (*Dr. Omalu Report* at 3 (emphasis added)).

In sum, Dr. Omalu's proffered testimony does not meet the "fit" requirement under *Daubert* and as recognized in the Third Circuit. The admission of Dr. Omalu's proffered testimony, which is based on a speculative set of facts and without a valid scientific connection, would not be helpful to the trier of fact.

F. Plaintiffs' Challenge to Exclusion of Dr. Omalu's Proffered Testimony Based on the Erie Doctrine

Plaintiffs also raise a novel argument as an alternative to the Defendants' challenges based on Federal Rule of Evidence 702 and *Daubert* and its progeny. (Docket No. 155). They contend that the application of several principles argued by the Defendants, if applied to exclude Dr. Omalu's testimony, would violate the *Erie* doctrine. The *Erie* doctrine provides that "[a] federal court sitting in diversity must apply state substantive law and federal procedural law." *Chamberlain v. Giampapa,* 210 F.3d 154, 158 (3d Cir. 2000); *Erie*, 304 U.S. at 78. Moreover, "[i]t is well-established that federal courts, when sitting in diversity, utilize" the Federal Rules of Evidence and Procedure. *Vaccaro v. HJC America, Inc., et al.*, Civ. A. No. 04-3480, 2007 WL 2990759, at *5 (D.N.J. Oct. 9, 2007). As one district court has summarized,

---

v. University of Pittsburgh Medical Center-Braddock Hosp., 950 A.2d 996 (Pa.Super. 2008).

> [u]nder *Hanna [v. Plumer]*, a federal court sitting in diversity first must determine whether a Federal Rule directly 'collides' with the state law it is being urged to apply. *Hanna [v. Plumer]*, 380 U.S. [460], 470-74, 85 S.Ct. 1136 [(1965)]. If there is such a direct conflict, the Federal Rule must be applied if it is constitutional and within the scope of the Rules Enabling Act. *See Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 427 n. 7, 116 S.Ct. 2211, 135 L.Ed.2d 659 (1996). If a 'direct collision' does not exist, then the court applies the *Erie* rule to determine if state law should be applied. *Hanna*, 380 U.S. at 470, 85 S.Ct. 1136. [emphasis in the original].

Velazquez v. UPMC Bedford Memorial Hosp., 328 F.Supp.2d 549, 552-53 (W.D.Pa. 2004).

In this action, Plaintiffs argue that the application of any of the following principles would violate Pennsylvania substantive law:

> (I) that an expert must rule out unknown or idiopathic causes of injury; (ii) that he may not rely upon a study showing less than a two-fold increased risk; and (iii) that he may not rely upon a study that is not statistically significant across a 95% confidence interval.

(Docket No. 155).

At the outset, the Court notes that Dr. Omalu's proffered testimony has not been excluded solely on these challenged bases, which were considered among a host of other deficiencies in Dr.Omalu's proffered testimony. In addition, this Court did not adopt any "bright-line" rules but instead evaluated the Plaintiffs' proffer of Dr. Omalu using a "flexible" approach as directed by the Court of Appeals in *Heller*. As a consequence, there is not a "direct collision" between the application of the federal procedural rules and state substantive law. Accordingly, Plaintiffs' argument must fail. However, the Court will briefly address their contention.

In support of their *Erie* doctrine argument, Plaintiffs rely on footnote 31 of *Paoli*, in which the Court of Appeals noted that "[w]e agree with the plaintiffs that because we are analyzing reliability for the purposes of litigation not for purposes of science, the substantive standard of

causation can affect the standard of admissibility." *Paoli*, 35 F.3d at 761 n.31. They argue that because the substantial factor standard of causation under Pennsylvania tort law is applicable in this diversity action, that the requirements that they rule out all alternative causes, including idiopathic cause, a study showing a relative risk of 2.0, and a ninety-five percent confidence interval, conflict with state tort law. (Docket No. 155).

Plaintiffs further argue that requiring Dr. Omalu to rule out idiopathic cause is tantamount to requiring him to rule out all alternative causes, and more than is required under the substantial factor test[19] in Pennsylvania. (*Id.*). The problem with Plaintiffs' logic, however, was addressed in *Paoli*. The issue is not that the burden under Pennsylvania law is slight or that any harm caused by Defendants could still result in a finding of liability under a multi-factorial causation scheme — the issue is that when an expert fails to rule out obvious alternative causes, or even consider them, as Dr. Omalu has done here, he is prevented from considering whether the alternative cause is the sole

---

[19] The "substantial factor" test for determining proximate cause was incorporated into the RESTATEMENT (SECOND) OF TORTS, § 431 (1965), which in turn has been adopted in Pennsylvania. *See Ford v. Jeffries*, 474 Pa. 588, 379 A.2d 111 (1977). In *Ford*, the Pennsylvania Supreme Court cited with approval the comments to § 431 of the Restatement which defined "substantial factor" as "conduct [that] has such an effect in producing the harm as to lead reasonable men to regard it as a cause, using that word in the popular sense ..." RESTATEMENT, *supra*, at § 431, comment a. *See Ford, supra*, at 595, 379 A.2d at 114.

Jeter v. Owens-Corning Fiberglas Corp, 716 A.2d 633, 636 (Pa.Super. 1998). Moreover, "[u]nder the law of Pennsylvania, a cause can be found to be substantial so long as it is significant or recognizable." *Id.* Further, "[a] plaintiff need not exclude every possible explanation and the fact that some other cause concurs with the negligence of the defendant in producing an injury does not relieve defendant from liability unless he can show that such other cause would have produced the injury independently of his negligence." *Jeter*, 716 A.2d at 637 (quoting *Jones v. Montefiore Hospital*, 494 Pa. 410, 416 (Pa. 1981)(internal quotations omitted).

cause of the injury, thereby undermining his entire medical causation opinion. In *Paoli*, the Court of Appeals explained:

> Here, however, if plaintiffs' experts failed to rule out alternative causes, it means that these alternative causes may have been the sole causes of plaintiffs' injuries-PCBs may not have played any role at all and certainly may not have been sufficient to bring about the plaintiffs' injuries. Testimony that PCBs increased the risk that plaintiffs would contract the injuries that they contracted does not show that PCBs were a substantial factor in those injuries. Moreover, testimony that plaintiffs' exposure to PCBs makes it likely that PCBs were a substantial factor in plaintiffs' injuries cannot reliably establish that PCBs were in fact a substantial factor unless the expert thought about the possibility that other potential causes of those injuries were in fact the sole cause of those injuries. Even under the substantial factor test, plaintiffs must prove that defendants' actions were a cause of plaintiffs' injuries before the burden switches to defendant to show that the injuries would have occurred even absent any action by the defendant.

Paoli, 35 F.3d at 761 n.31. Moreover, this Court has considered the decisions cited by Plaintiffs, including *Ford v. Jeffries*, 379 A.2d 111 (Pa. 1977), and is in agreement with the Court of Appeals' statement in *Paoli* that "Pennsylvania substantive law does not change the federal standard for the admissibility of expert testimony." *Id*. Thus, Federal Rule of Evidence 702 must be applied to this action.

As to Plaintiffs' argument regarding the supposed requirement that an association be demonstrated with ninety-five percent (95%) statistical significance, because the Court has excluded Dr. Omalu's statistical re-analysis of the 2004 Lee Study, there is no evidence of record supporting any factor less than ninety-five percent.[20] With respect to the relative risk requirement to which

---

[20] Further, to the extent Plaintiffs contend that "a requirement that experts eschew studies that are not statistically significant over a 95% confidence interval is contrary to the Pennsylvania caselaw permitting expert testimony, including testimony as to increased risk, based upon merely

Plaintiffs object, again, the Court did not impose or adopt the 2.0 relative risk standard in this case.

The Court also finds instructive decisions by two District Judges in this District, former District Judge and current Circuit Judge D. Brooks Smith, and District Judge Kim Gibson, which have rejected similar arguments in the context of Federal Employer's Liability Act ("FELA") litigation. *See e.g., Snyder v. Consolidated Rail Corporation*, No. C.A. 94-11J, 1998 WL 465897, at *6 (W.D.Pa. Aug.4, 1998)(Smith, J.), *Wicker v. Consolidated Rail Corporation*, 371 F.Supp.2d 702, 712-15 (W.D.Pa. 2005)(Gibson, J.). As noted by Judge Smith, a FELA case "has a more lenient standard for determining negligence and causation" than a tort action under Pennsylvania law. *Snyder*, 1998 WL 465897, at *6. Therefore, as *Daubert* and Rule 702 apply in FELA cases, which involve a lower causation standard than Pennsylvania tort law, one can logically infer that there is no conflict between the federal procedural rules and Pennsylvania substantive law in this case.

IV. CONCLUSION

Based on the foregoing, Defendants' Motion to Exclude the Expert Testimony of Dr. Bennet Omalu [127] is GRANTED. Thus, Dr. Omalu's proffered testimony is excluded. An appropriate Order follows.

s/Nora Barry Fischer
Nora Barry Fischer
United States District Judge

Dated: March 11, 2010

cc/ecf: All counsel of record.

'reasonable' certainty," (Docket No. 155 at 11), the Court rejects same as Dr. Omalu's testimony, which is based on speculation and conjecture, is not made to a reasonable certainty. *See* n. 18 *supra.*